REMARKS

Claims 1 – 21 are currently pending. Claims 1, 18, 19, and 21 are the pending independent claims. Of these, Claim 21 is newly added. In the Office Action, Claims 1-17 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 4,929,605 to Domet et al. ("Domet") in combination with U.S. Patent No. 4,176,175 to Maekawa et al. ("Maekawa"). Finally, Claims 18-20 were rejected as allegedly obvious over Domet in combination with U.S. Patent No. 6,380,381 to Obara et al. ("Obara").

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

I. The Prior Art Rejections of Claims 1 – 17.

Claims 1-17 were again rejected as allegedly obvious over Domet in combination with Maekawa. The previously noted distinctions between the subject matter of Claims 1 – 17 and the hypothetical combination of the Domet and Maekawa patents still apply.

Independent Claim 1 (and therefore, by definition, each of its dependent claims) calls for a pharmaceutical composition in the form of at least a tablet core which consists essentially of: (1) *fexofenadine* or a pharmaceutical acceptable acid addition salt thereof, (2) about 10 wt. % to about 70 wt. % of *lactose*, and (3) about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, all of which are dispersed within the core.

Again, neither Domet nor Maekawa even mentions fexofenadine, which is the active pharmaceutical substance in the claimed composition. While the Domet patent does refer in general terms to piperidinoalkanol derivatives, Domet clearly and unambiguously states that his preferred piperidinoalkanol derivative is terfendaine, not fexofenadine. Thus a person of ordinary skill applying the teachings of Domet would use is terfendaine, not fexofenadine, absent some contrary teaching in a supporting reference. The Examiner has pointed to no such contrary teaching. The absence of this teaching speaks loudly.

Further, the Domet patent does not suggest a tablet core which contains a dispersion of lactose and low-substituted hydroxypropyl cellulose as the Examiner concedes. The Examiner attempts to cure these defects with the Maekawa patent.

The Maekawa patent, however, says absolutely nothing about lactose. While Maekawa makes a general reference to use of "sugar", the only sugar specifically referred to in Maekawa

is sucrose, not lactose. Consequently, then, one of skill following the teaching of Maekawa would have been lead to use sucrose, not lactose, since this was clearly Maekawa's preferred (and apparently only) embodiment. Again, when a reference is cited in an obviousness rejection, the reference must be taken as a whole for all that it teaches, plus what it does not teach. *See In re Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965)..

In addition, the Applicants have herein amended the claims to clarify that the fexofenadine (or a pharmaceutical acceptable acid addition salt thereof), lactose, low-substituted hydroxypropyl cellulose are dispersed in a tablet core. This provides yet another distinction between the subject matter of the claims and the teachings of Demot and Maekawa. The sugars and low-substituted HPC disclosed in Maekawa are applied as an outer coating. Neither is dispersed in a tablet core as called for in the presently amended claims. For this reason, Maekawa cannot reasonably be said to teach the subject matter of Claims 1 – 17.

In view of these failings of Domet and Maekawa, it is respectfully submitted that their purported combination cannot fairly be said to have been "obvious," nor can it be said (fairly or otherwise) to suggest Applicants' pharmaceutical composition as defined in independent Claim 1 and its dependent claims. Thus, the obviousness rejections of these claims based upon Domet and Maekawa are not well founded and should be withdrawn.

II. The Prior Art Rejections of Claims 18 – 20.

Finally, Claims 18-20 were rejected as allegedly being obvious over Domet in Obara et. It is again submitted that these rejections are also unfounded and should be withdrawn.

Independent Claims 18 and 19 are each directed to a method for preparing a pharmaceutical composition which consists essentially of (1) fexofenadine or a pharmaceutical acceptable acid addition salt thereof, (2) about 10 wt. % to about 70 wt. % of lactose, and (3) about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose. In both claims, the first step recited in the method is "mixing fexofenadine, lactose, and low-substituted hydroxypropyl cellulose to form a premix." This is not disclosed or suggested in Domet or Obara, either individually or taken in combination.

As noted above, the primary reference Domet fails to disclose the active ingredient fexofenadine. Instead Domet teaches that a preferred piperidinoalkanol derivatives is

terfendaine, not fexofenadine. Further, Domet teaches neither the use of lactose nor the use of and low-substituted hydroxypropyl cellulose in his pharmaceutical composition.

As for the Obara patent, this reference merely discloses"low-substituted hydroxypropyl cellulose having good granulation characteristics and tablet properties." *See* Obara, Col. 1, lines 6 – 8. Obara says nothing about using this low-substituted hydroxypropyl cellulose with fexofenadine or any other form of piperidinoalkanol derivative. In fact, Obara does not specify any form of active pharmaceutical ingredient which is said to be suitable for use with the low-substituted hydroxypropyl cellulose described therein. Accordingly, there would have been no reason or incentive for a person of ordinary skill in the art to have modified the teachings of Domet based upon the disclosure of Obara.

The mere fact that various references (in the Examiner's view) might separately mention the components of the premix recited in Claims 18 – 20 does not make it obvious to combine these components as called for in the present claims. Otherwise, virtually every mixture ever claimed would be obvious if one could find the components somewhere. This is not consistent with our law. As the Supreme Court recently explained,

> a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

KSR Intern. Co. v. Teleflex Inc., 127 S.Ct. 1727, 1741 (2007). Thus, in the words of the Federal Circuit,

> "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"

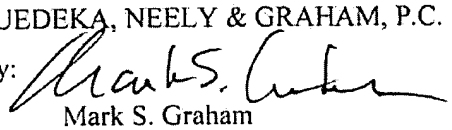
See In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006) (Cited with approval in *KSR*). Such reasoning is lacking in the present case and consequently, the hypothetical combination of the Domet and Obara references cannot lawfully render Claims 18 – 20 obvious.

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

LUEDEKA, NEELY & GRAHAM, P.C.

By: 

Mark S. Graham
Registration No. 32,355

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P.O. Box 1871
Knoxville, Tennessee 37901
(865) 546-4305

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